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case resulted in a verdict in favor of plaintiff and against Playtex in the amount of \$1.25 million compensatory damages, after a 20% reduction for medical malpractice by the treating physician, and \$10 million punitive damages. The jury based its verdict on findings that Playtex Super Deodorant Tampons being used by O'Gilvie at the time of her death contributed to the cause of TSS and created increased risk which was not adequately disclosed in the warnings.

Columbia has provided affidavits from experts who say that the representations in the 1984 specifications are misleading and inaccurate with regard to the relationship between TSS and tampon use.

Columbia's underwriter, Richard S.W. White, has submitted an affidavit in which he states that he did not read the specifications related to TSS in 1985. It is undisputed that Mr. Stein, Esmark's insurance agent, ultimately placed comprehensive general liability excess coverage with Columbia excluding TSS coverage for Playtex.

Playtex's first argument is that the statute of limitations bars the counterclaim.

Delaware has a three-year "accrual" statute of limitations for fraud. 10 Del.C. § 8106. This statute applies to counterclaims seeking affirmative relief. DiNorscia v. Tibbett, Del.Super., 124 A.2d 715 (1956). A cause of action for fraud accrues when the fraud is successfully perpetrated. Tobacco & Allied Stocks v. Transamerica Corp., D.Del., 143 F.Supp. 323, 328 (1956), *aff'd*, 3d Cir., 244 F.2d 902 (1957). Columbia claims that Playtex's fraud induced the issuance of a policy effective October 1, 1984. Thus, unless tolled, the statute of limitations on Columbia's claim of fraudulent inducement expired on October 1, 1987.

*4 Ignorance of the facts supporting a cause of action will not toll the statute, absent some special consideration such as "inherently unknowable" injuries or fraudulent concealment. See, e.g., Mastellone v. Argo Oil Corp., Del.Super., 82 A.2d 379 (1951); Freedman v. Beneficial Corp., D.Del., 406 F.Supp. 917 (1975); Halpern v. Barran, Del.Ch., 313 A.2d 139 (1973). The burden of showing that the statute should be tolled rests with the party asserting the tolling. Freedman v. Beneficial Corp., D.Del., 406 F.Supp. 917 (1975).

A wealth of information regarding TSS was generally

available in 1984. Consequently, there is no basis to conclude that the information about the relationship between TSS and tampons was inherently unknowable to Columbia. Columbia did not ask Playtex to complete an application. Columbia did not ask for additional information. Indeed, Columbia acknowledges that no attempt was made to develop information beyond that provided in the 1984 specifications. Therefore, that basis for tolling the statute of limitations has no application.

The second way to toll the statute of limitations is through a showing that there has been fraudulent concealment of the facts necessary to put a party on notice of the truth.

In Bradley v. Maryland Casualty Co., D.Del., 563 F.Supp. 602 (1983), Judge Latchum quoted then-Chancellor Duffy's outline of the law of Delaware concerning fraudulent concealment as a basis for tolling the statute of limitations as follows:

Fraudulent concealment of a cause of action is an independent ground for tolling a statute of limitations. Where there has been fraudulent concealment from a plaintiff, the statute is suspended only until his rights are discovered or until they could have been discovered by the exercise of reasonable diligence. Fraudulent concealment requires that something affirmative be done by a defendant, some "actual artifice" which prevents a plaintiff from gaining knowledge of the facts or some misrepresentation which is intended to put the plaintiff off the trail of inquiry. Mere ignorance of the facts by a plaintiff, where there has been no such concealment, is no obstacle to operation of the statute.

Quoting Halpern v. Barran, 313 A.2d at 143 (emphasis supplied). See also Shockley v. Dyer, Del.Super., 456 A.2d 798 (1983).

Columbia argues that it had no duty to inquire into possible fraud and misrepresentations by Playtex until, at the earliest, April 3, 1987, when it received notice of a potential TSS claim from Playtex. In support of that contention, it relies on Borden v. Paul Revere Life Ins. Co., 1st Cir., 935 F.2d 370 (1991), in which the Court held that it was reasonable for the insurer not to discover misrepresentations on the insured's application before coverage was sought, noting:

In the case at bar, the jury could well have found that Revere [the insurer] exercised reasonable diligence when scrutinizing the results of Borden's medical questionnaire. The completed form did not mention,

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or even hint at, Borden's serious back problems. An insurance company cannot routinely be expected to prove a negative, that is, to verify the undisclosed medical history of every applicant. Here, Revere had no cause to suspect that, in answering the questionnaire, Borden was whitewashing his past. At least until Borden sued, Revere had no overwhelming incentive to go behind his unequivocal representations about the state of his health.

*5 *Id.* at 376.

Borden involves a man who secured disability insurance, then suffered an injury which left him disabled. He sought benefits. The insurer believed that the nature of his work had been improperly described on the initial application as more managerial than it actually was. During discovery, the insurer learned that Borden had suffered a prior back injury. After a trial, the Court was asked to determine whether the statute of limitations barred Borden's claim. The Court found that the prior back complaint was inherently unknowable in view of the information provided on the application. The statute of limitations applied.

Borden does not stand for the proposition that no duty of inquiry arises until there is a claim. *Borden* is distinguishable. Unlike Playtex's specifications which give much more than a passing reference to TSS claims, Borden made no mention of back problems in response to questions on an application designed to elicit such information.

Columbia relies on *Bradley v. Maryland Casualty Co.*, 563 F.Supp. at 607 for the proposition that "Mere suspicion or rumor ... will not put a plaintiff on [inquiry] notice." In *Bradley* there was evidence that the insurer of a man entitled to receive workmen's compensations benefits was actively concealing the fact that he was entitled to receive certain additional benefits for nursing services. The Court found that there was an issue of material fact which prevented a determination as a matter of law as to whether or not the plaintiffs failed to exercise due diligence in discovering the fraudulent concealment.

Bradley is analogous. The evidence available to Columbia with regard to TSS was concrete. Claims were being paid and had been paid for a period of several years. Substantial losses were being handled by a national coordinating counsel and by an independent insurance adjuster. The fact that there was a product recall and a substantial punitive damages verdict was revealed in 1985. A plan to

insure TSS cases and then initiate a recall was not suggested.

Columbia also notes that due diligence is not required "in the abstract."

The requirement of diligence is only meaningful ... when facts exist that would excite the inquiry of a reasonable person.... Due diligence is not required in the abstract. Plaintiffs are not under a duty continually to scout around to uncover claims which they have no reason to suspect they might have.

In re Coordinated Pretrial Proceedings, C.D.Cal., 782 F.Supp. 487, 497-98 (1991). *Coordinated Pretrial* involved an anti-trust claim in which a statute of limitations defense was asserted. The plaintiffs alleged that the defendants had fraudulently concealed their price fixing conspiracy. In the context of a summary judgement motion, the court held that although the underlying facts were essentially undisputed, there were factual issues as to the inferences to be drawn from the facts. Summary judgment was denied.

*6 Columbia alleges that the 1984 specifications were misleading. It argues that the information supplied, when combined with the custom and practice in the industry regarding an insured's obligation to give full and fair disclosure, was calculated to take Columbia "off the trail of inquiry" regarding the risks associated with TSS claims. If there is evidence of a secret plan to recall the tampons, it would constitute a misrepresentation, material in nature, sufficient to raise a factual issue which would preclude summary judgment.

The key evidence in support of the alleged misrepresentation comes from Michael Liles. Columbia discovered Michael Liles when it learned of a consulting agreement between Liles and Playtex which occurred after the commencement of this litigation. Liles and his "bubble document" ^{FN2} have been the subject of discussion in prior opinions. *Playtex, Inc. v. Columbia Casualty*, C.A. No. 88C-MR-233, Del Pesco, J. (July 10, 1992), Letter Op. at 8-11. For purposes of deciding whether to require the production of privileged documents, the Court determined on July 10, 1992, that Columbia had not made "a showing of a factual basis of fraudulent activity adequate to support a good faith belief by a reasonable person that the documents sought will prove a fraud." *Id.* at 11. However, that holding, in the context of a discovery dispute, does not represent a factual finding on the merits. The conclusion that the privileged documents would not likely prove a

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fraud does not mean that a fraud cannot be proven at trial. Therefore, law of the case does not apply.

FN2. The document is often referred to as the “bubble document” because its text allegedly refers to bursting the bubble of another plaintiffs’ attorney, Mark Hutton, as to the reason for the Playtex P-2 tampon recall.

Playtex argues that Columbia has no evidence of a fraud without the Liles evidence and the Liles evidence is inadmissible.

First, it’s important to distinguish between the two components of the Liles evidence: the “bubble document” and the consulting agreement.

Liles claims that the punitive damages theory he developed in the context of liability claims against Playtex—that the tampon recall of 1985 was not the result of the *O’Gilvie* case but rather a plan that had been developed in 1983—was validated by a document he saw at the Playtex depository (“bubble document”). He further claims that he requested a copy of the “bubble document,” but that it was never provided to him. Such a document, depending on its author, could be evidence of a misrepresentation.

The second component of the Liles evidence is the fact that Playtex entered into a consulting agreement with Liles which took him out of TSS litigation. Columbia seeks to present “Liles’ testimony concerning *all* of Playtex’s conduct that culminated in its extraordinary \$500,000 payoff.” Columbia seeks to prove that Playtex was seeking to silence Liles to keep him from talking to insurance companies.

The first issue is the admissibility of the content of the “bubble document.” If it could be shown to be an admission, it would not be hearsay. However, Liles cannot identify the Bates number, the author, the box, the recipient, or even say for certain that the “bubble document” was written by a Playtex employee. The best Liles can offer is that the author has a name like “fettucini.” The document is not an admission because Columbia cannot establish that the conditions of Delaware Uniform Rule of Evidence (“DURE”) 801(d)(2)(C) or (D) have been met. *See, e.g., Reese v. Montgomery & Co., Inc.*, Del.Super., C.A. No. 79A-AU1, Tease, J. (Mar. 1, 1981); *Carden v. Westinghouse Elec. Corp.*, 3d Cir., 850 F.2d 996 (1988); *Miller v. Keating*, 3d Cir., 754 F.2d 507 (1985) (utterance of unidentified declarant not

admissible under F.R.E. 803(2)). On this record, the document does not contain an admission.

*7 If the document is hearsay, it can be admitted only if some exception applies. Columbia argues that the content of the document should be admitted because it is not offered for the truth of the matter asserted but rather to prove the effect of Liles’ discovery of the document upon Playtex. However, it is clear that the content is offered to prove the truth of the matter asserted and that his knowledge of the undisclosed plan had further consequences.

Columbia argues that the content of the “bubble document” is admissible because Playtex has destroyed the document or otherwise made it unavailable. In support of this assertion, Columbia relies on spoliation cases in which the destruction of a relevant and admissible document was conceded. Here, the destruction is denied; indeed, the very existence of the document and the alleged request for a copy are denied. The spoliation rule has no application until there is a factual foundation that there has been a destruction of evidence, and that it was intentional and in bad faith. Such a conclusion is not supported by the present record. *See, e.g., State v. Langlet*, Iowa, 283 N.W.2d 330, 335-36 (1979); *Moore v. General Motors Corp.*, Mo.Ct.App., 558 S.W.2d 720, 736 (1977) (must have *prima facie* showing of fraud, deceit or bad faith).

The alleged content of the “bubble document” is not admissible because it is hearsay and does not fall within any applicable exception.

The second part of the Liles evidence relates to Liles’ testimony that he told Playtex’s attorneys that he had seen a document that validated his theory of a 1983 recall plan and the consulting agreement followed. Columbia seeks to prove that Playtex was attempting to hide information from its insurers (information which shows that Playtex was aware of the unique TSS risks posed by its tampons), had a secret plan to protect itself from those risks, had implemented a recall, and had defrauded its insurers as part of that course of conduct. All such evidence is relevant; the inferences to be drawn from the evidence are left to the fact finder.

There is a factual issue sufficient to preclude summary judgment on the fraud/misrepresentation counterclaim.

Playtex argues that summary judgment is appropriate on the affirmative defense of misrepresentation

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because it is clear that there could be no justifiable reliance on the specifications when so much information regarding TSS was available from other sources. If Columbia's case were limited to the face of the specifications, Playtex's argument would be persuasive. While it may be assumed, arguendo, that Columbia could develop information about TSS beyond that provided in the specifications, the fact is that a planned recall of a product, if there were such a plan, could be highly material to both a liability carrier and a recall carrier. Therefore, the same factual issue precludes summary judgment on the justifiable reliance argument.

II. NEGLIGENT MISREPRESENTATION

*8 Playtex seeks summary judgment on Columbia's claim for negligent misrepresentation. Two arguments are presented. The first, which is similar to Playtex's other fraud and misrepresentation claims, is that there is no justifiable reliance. This argument is rejected for the same reason as previously set forth in connection with the fraud claim.

Secondly, Playtex argues that there is no cognizable claim of negligent misrepresentation under Delaware law for a commercial relationship of this type, citing *Danforth v. Acorn Structures, Inc.*, Del.Super., C.A. No. 90C-JN-30, Herlihy, J. (Nov. 22, 1991), *affirmed and remanded*, Del.Super., 608 A.2d 1194 (1992). *Danforth* considers the application of Section 552 of the Restatement (Second) of Torts ^{FN3} to a custom design agreement which contained defective plans to build a house and a home building package. The Court held that § 552 did not apply:

FN3. Section 552 states as follows:

Information Negligently Supplied for the Guidance of Others

(1) One who, in the course of his business, profession or employment, or in any other transaction in which he has a pecuniary interest, supplies false information for the guidance of others in their business transactions, is subject to liability for pecuniary loss caused to them by their justifiable reliance upon the information, if he fails to exercise reasonable care or competence in obtaining or communicating the information.

(2) Except as stated in Subsection (3), the liability stated in Subsection (1) is limited to loss suffered

(a) by the person or one of a limited group of persons for whose benefit and guidance he intends to supply the information or knows that the recipient intends to supply it; and

(b) through reliance upon it in a transaction that he intends the information to influence or knows that the recipient so intends or in a substantially similar transaction.

(3) The liability of one who is under a public duty to give the information extends to loss suffered by any of the class of persons for whose benefit the duty is created, in any of the transactions in which it is intended to protect them.

Thus, it is clear that in order to invoke a cause of action under negligent misrepresentation involving § 552, the plaintiff must show that the defendant supplied the information to the plaintiff for use in business transactions with third parties. In other words, the information must be used in a transaction not involving the defendant.

Danforth's claim fails on this ground alone. He did not and does not claim that he took Acorn's information in the agreement and in *any way* used that with a third party.... Accordingly, on this ground, Danforth's negligent misrepresentation claim must fail. *Id* at 4.

Columbia asks this Court to reject the holding in *Danforth*, and to apply § 552 to this insurance contract transaction. It is clear that § 552 contemplates that the advice given by the alleged tortfeasor be relied upon by the injured party in a transaction with a third party. That is the context in which negligent misrepresentation has been permitted in other Delaware cases. *Hodges v. Smith*, Del.Super., 517 A.2d 299 (1986); *Guardian Construction Co. v. Tetra Tech Richardson, Inc.*, Del.Super., 583 A.2d 1378 (1990).

Danforth properly sets forth the law in Delaware. Playtex's motion for summary judgment on the negligent misrepresentation claim is GRANTED.

III. "STEIN FRAUD" ISSUE

Playtex argues that it is entitled to summary judgment on Columbia's allegation that Phillip Stein, an insurance broker acting on behalf of Esmark, told Richard White, a Columbia underwriter, that if the first layer of insurance was a fronting policy, the

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policy would contain a per occurrence policy limit of one million dollars, with total liability under the policy limited to seven million dollars in the aggregate. Stein also allegedly represented that the policy would contain a one million dollar maintenance deductible for each and every occurrence, without limit ("Stein fraud" issue).

Playtex denies that the maintenance deductible was ever intended or represented to be nonaggregating.

This Court has previously had occasion to consider the intent of the maintenance deductible. *Playtex FP, Inc. v. Columbia Casualty Co.*, C.A. No. 88C-MR-233, Del. Pesca, J. (Dec. 9, 1991) (ORDER). That opinion concluded:

*9 [T]he intent of Esmark, Northwestern and Mission for the Northwestern policy to be an articulation of Esmark's self-insured retention. Therefore the Mission policy attaches after Esmark has paid \$1 mill per occurrence to an aggregate of \$7 million for toxic shock losses. *Id* at 26.

The same opinion notes that although Columbia's intent was not controlling, no factual determination as to Columbia's intent was made.

At this juncture, the Court is asked to dismiss the Stein fraud portion of Columbia's counterclaim because the Mission policy which was delivered to White clearly indicated there was no nonaggregating deductible. The law is clear that the purpose of placing the terms of insurance coverage in writing and delivering the policy representing the contractual undertaking of the issuer to the insured is so the insured will know the scope of the coverage provided. *Kaufman v. C.L. McCabe & Sons, Inc.*, Del.Super., 603 A.2d 831 (1992). It is a logical corollary that an excess insurer that follows form to a primary carrier must read a policy that it has agreed to underwrite and cannot claim that the absence of a provision was unknown or unknowable.

Summary judgment on the grounds that Columbia cannot show justifiable reliance on the alleged promises of Stein need not be reached. The fact that the Mission policy was delivered to Columbia at about the time coverage commenced justifies the entry of summary judgment on the grounds that this claim was asserted beyond the statute of limitations. *10 Del.C. § 8106*.

Playtex's motion for summary judgment on the Stein fraud issue is GRANTED.

IV. "OCCURRENCE" LANGUAGE

Playtex seeks summary judgment on Columbia's defense that coverage is precluded as not being an "occurrence" within the scope of the policy.

The Mission policy, to which Columbia follows form, agrees:

to indemnify the insured for all sums which the insured shall be obligated to pay by reason of liability ... on account of: 1. personal injury, ... caused by or arising out of an occurrence....

The policy further states:

The term "occurrence" applicable to personal injury and property damage means an accident or a happening or an event, or continuous or repeated exposure to conditions, which results in personal injury or property damage, neither expected nor intended from the standpoint of the insured against whom the resulting claim is presented.

This policy is an "occurrence" policy. Under an "occurrence" policy, "the insured is indemnified for acts or occurrences which take place within the policy period ..." *Appalachian Ins. Co. v. Liberty Mut. Ins. Co.*, 3d Cir., 676 F.2d 56, 59 (1982). The insurer's duty to indemnify the insured is triggered by a determination that fortuitous ^{FN4} bodily injury or property damage occurred during the policy period.

^{FN4}. [A] fortuitous event is an event which, so far as the parties to the contract are aware, is dependent on chance.... The thrust of the definition is that the occurrence be unplanned and unintentional in nature. *RESTATEMENT OF CONTRACTS § 291* comment a (1932). See *Peters Township School District v. Hartford Accident & Indem. Co.*, 3d Cir., 833 F.2d 32 (1987) (adopting Restatement definition).

It is a general rule that one cannot obtain insurance for those losses which are not fortuitous, in other words, for those losses of which the insured knows, plans, intends, or is aware. See, e.g., *Intermetal Mexicana v. Insurance Co. of North America*, 3d Cir., 866 F.2d 71 (1989) ("The fortuity doctrine arises from the basic concept that insurance covers risks, rather than losses that were planned, intended, or

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anticipated by the insured.”); Bartholomew v. Appalachian Ins. Co., 1st Cir., 655 F.2d 27, 29 (1981) (“The concept of insurance is that the parties, in effect, wager against the occurrence or non-occurrence of a specified event; the carrier insures against a risk, not a certainty.”). It has been held to be contrary to public policy for an insurance company to knowingly assume the burden of a loss that occurred prior to making the contract. Burch v. Commonwealth County Mutual Ins. Co., Tex., 450 S.W.2d 838, 840 (1970).

*10 In determining whether an insured's claims are fortuitous, the court must determine whether the insured attempted to insure itself against *known losses* or merely against *known risks*. There can be no liability insurance coverage for those *losses* that the insured knew about when the policy was issued. On the other hand, insurance may provide financial protection against those *risks* which may someday occur. “Knowledge of a risk is not the same as knowledge of a loss.” Liberty Mutual Insurance Co. v. SCA Services, Inc., Mass.Super.Ct., No. 88-6575 (Oct. 12, 1989).

Playtex is seeking indemnification only for claims that occurred after the inception date of the policy.

The Mission policy, which mirrors standard comprehensive general liability policies, requires that a loss be neither “expected” nor “intended” from the standpoint of the insured. The district court in New Castle II, construed the “neither expected nor intended” language in the “occurrence” clause to bar coverage only if, before the policy period begins, “there is evidence ... indicating a *substantial probability* that a loss will occur.” New Castle County v. Hartford Accid. & Indem. Co., D.Del., 685 F.Supp. 1321, 1330 (1988) (emphasis added).

Columbia argues that proof of Playtex's recklessness is sufficient to establish a “substantial probability” of losses, and therefore its losses are not covered “occurrences” under the policy. Columbia relies on the New Castle County case to support its argument. Columbia's reliance is misplaced. In New Castle County, the loss which eventually occurred, groundwater contamination resulting from the operation of a landfill, was in progress before the policy period began. It is well established that losses in progress are not occurrences. Summers v. Harris, 5th Cir., 573 F.2d 869 (1978); See also Stonewall Insurance Company v. National Gypsum Co., S.D.N.Y., C.A. No. 86 Civ. 9671, Bernikow, U.S. Mag. (Dec. 31, 1991), 1991 WL 320046, at *9.

Mere foreseeability of potential losses is not enough. U.S. Fire Ins. Co. v. CNA Ins. Co., Ill.App.Ct., 572 N.E.2d 1124, 1130 (1991). In fact, insurance is obtained to protect against mishaps that are expected. See City of Johnstown v. Bankers Standard Ins. Co., 2d Cir., 877 F.2d 1146, 1150 (1989). Both Playtex and Columbia anticipated that there would be claims during the 1984-85 policy year. However, it is not disputed that although the risk was known, the specific individuals who would be asserting such claims and experiencing such losses and the specific nature of the losses were not known or knowable at the time the policy inception. Stonewall Insurance Company v. National Gypsum Co., 1991 WL 320046, at *10-11. Nor was it possible for Playtex to know the kind or extent of the subsequent losses. U.S. Fire Ins. Co. v. CNA Ins. Co., 572 N.E.2d at 1130.

Playtex's motion for summary judgment on the occurrence defense is GRANTED.

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END OF DOCUMENT

EXHIBIT 8

Westlaw.

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HBriefs and Other Related Documents

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United States District Court, E.D. Pennsylvania.
 In Re Products Liability Litigation This Document
 Relates To All Actions
 This Document Relates To All Actions.
No. MDL 1014.

Aug. 22, 1996.

MEMORANDUM AND ORDER

BECHTLE, J.

*1 Presently before the court are Defendants' motions to dismiss the conspiracy and fraud claims in Plaintiffs' Omni Complaints, and Plaintiffs' opposition thereto. For the reasons set forth below, the court will dismiss all PLC Omni Actions ^{FN1}, without prejudice, under Federal Rule of Civil Procedure 12(b)(1) because Plaintiffs have not proven that the court has jurisdiction over the subject matter of the claims. In addition, the court will dismiss all conspiracy claims in the PLC Omni Actions, ^{FN2} without prejudice, under Rule 12(b)(6) because the claims fail to state a claim upon which relief can be granted. The court will dismiss the conspiracy claims in the Lestelle Omni Actions, without prejudice, under Rule 12(b)(6) because they fail to state a claim upon which relief can be granted, and under Rule 9(b) because the circumstances of fraud are not averred with sufficient particularity. The court will dismiss all fraud claims in the Lestelle Omni Actions under Rule 9(b), without prejudice, because the circumstances of fraud are not averred with sufficient particularity.

^{FN1}. By "PLC Omni Actions," the court is referring to Omni lawsuits that have been filed by Plaintiffs who are represented by members of the Plaintiffs' Legal Committee.

^{FN2}. By "Lestelle Omni Actions," the court is referring to Omni lawsuits that have been filed by Plaintiffs who are represented by Louisiana lawyer Andrea Lestelle ("Lestelle") and her colleagues.

I. BACKGROUND

The court will not attempt to summarize the lengthy and detailed factual and procedural history of this multidistrict litigation. The facts pertinent to this Order are as follows. On October 15, 1995, Plaintiffs filed the first of some 650 complaints that the parties and the court have referred to as the "Omni" complaints. The Omni complaints are like any other complaints in this case to the extent that each Plaintiff seeks damages from the manufacturer of the fixation device that was implanted into the Plaintiff's spine as well as the doctors and companies who designed or distributed the particular device. To this end, Plaintiffs allege that these Defendants are liable under theories that include strict product liability, negligence, breach of express warranty, illegal marketing and promotional activities, intentional and negligent infliction of emotional distress, and failure to warn.

The Omni complaints are different because each Plaintiff's claims are not confined to the manufacturer, designer, or distributor of the actual device that was implanted in the Plaintiff's spine. Rather, most of these pleadings name as Defendants dozens of individuals, corporations, and associations that were not involved in the design, manufacture, or sale of the particular product. Thus, the Omni Plaintiffs essentially seek to recover from the entire spinal fixation device industry under the theories that all of its members engaged in conspiracy, concert of action, aiding and abetting, enterprise liability, and fraud on the marketplace. ^{FN3}

^{FN3}. In addition, the PLC and Lestelle Omni Actions have improperly joined as many as 110 individual plaintiffs in a single complaint. The court has dealt with this misjoinder problem separately in Pretrial Order No. 441.

The court has found that there are two forms of Omni complaints. One form is used by members of the Plaintiffs' Legal Committee ^{FN4} ("PLC") and the other is used by Lestelle and her colleagues. Lawyers representing both groups have informed the court that the language and allegations of the complaint forms in their respective groups are basically the same.

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FN4. The PLC speaks for nearly all Plaintiffs' counsel on nearly all issues in this case. However, on some issues, a minority of Plaintiffs' counsel have disagreed with the PLC's position.

*2 The PLC Omni complaint form is the more sweeping of the two. It names as Defendants, in addition to the maker of the spinal fixation system and its subsidiaries, companies that allegedly distributed the spinal fixation devices on the manufacturer's behalf. It seeks damages from persons and entities who assisted the manufacturers in obtaining approval from the United States Food and Drug Administration ("FDA") to market spinal fixation devices for use in parts of the body other than the pedicle of the spine (the "regulatory consultants"). The PLC pleading also set forth claims against doctors who allegedly promoted such devices on behalf of the manufacturers (the "doctor-promoters"). Finally, this complaint form names as Defendants various spinal associations that arranged seminars at which the doctor-promoters taught other physicians how to implant the devices (the "promotional centers"). The PLC alleges that all these Defendants are liable for injuries caused by the implanted device because they conspired to sell and market spinal fixation devices for use in the pedicle of the spine, even though the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § § 301 *et seq.*, prohibits persons from selling and marketing such devices for that use. See 21 U.S.C. § § 331(a), (b) (prohibiting the adulteration or misbranding of any device in interstate commerce and the introduction into interstate commerce of any adulterated or misbranded device); 351(f)(1)(B)(i) (providing that adulterated devices include devices that have been classified as class III devices and must have "premarket approval"); 352 (describing the categories of devices that are misbranded); see also 21 U.S.C. § § 333(a) (establishing criminal penalties for violating § 331); 360c(a)(1)(C) (describing which devices fall into the class III category).

The Lestelle Omni complaint form sets forth narrower, more focused claims in this regard. It alleges no claims against regulatory consultants or promotional centers and does not seek to hold the other Defendants liable for aiding and abetting or enterprise liability. It alleges only a horizontal conspiracy in which the manufacturers "acted in agreement" to fraudulently create an illegal market for the pedicle screw devices.

Defendants have responded to the Omni complaints with motions to dismiss. These motions are based on a variety of grounds, including lack of subject matter jurisdiction, lack of personal jurisdiction, violation of First Amendment protection, immunity under the Eleventh Amendment, and failure to state a claim upon which relief can be granted. Because of the quantity of the Omni complaints and the quantity and complexity of the challenges to them, the court began to organize a process by which Defendants' motions could be argued and briefed. On April 11, 1996, the court randomly selected three Omni complaints to consider at a preliminary hearing on the motions to dismiss. (Tr. 4/11/96 at 39-42.) The court chose the following cases: *Fuselier v. Danek Medical*, No. 96-547 (S.D. Tex. filed Oct. 23, 1995); *Hoffpauir v. Acromed Corp.*, No. 96-918 (W.D. La. filed Dec. 1, 1995); and *Thomas v. Acromed Corp.*, No. 96-936 (E.D. La. filed Dec. 11, 1995). (Pretrial Order No. 298 ¶ 3.) Probably because the PLC Omni Actions outnumber the Lestelle Omni Actions by about ten to one, the three chosen cases were PLC Omni Actions. The court also has reviewed three representative Lestelle Omni Actions titled *Durbin v. Advanced Spine Fixation Sys., Inc.*, No. 96-2258 (C.D. Cal. filed Jan. 29, 1996); *Acosta v. Advanced Spine Fixations Sys., Inc.*, No. 96-2246 (C.D. Cal. filed Dec. 29, 1995); *Hall v. Advanced Spine Fixation Sys., Inc.*, No. 96-2261 (C.D. Cal. filed Dec. 29, 1995).^{FN5}

FN5. To keep matters simple, the court will cite to portions of the PLC Omni Actions by citing to the Complaint in the *Fuselier* case. The court will cite to portions of the Lestelle Omni Actions by referring to the "First Amended Complaint for Damages" filed in the *Durbin* case.

*3 At a hearing on April 19, 1996, the court expressed its concern that the Plaintiffs may have pleaded the conspiracy claim in the Omni complaints too generally. (Tr. 4/19/96 at 26-27.) The court told Plaintiffs that it wanted them to demonstrate that the Omni complaints averred fraud with sufficient particularity to satisfy Rule 9(b) and that counsel had sufficient evidence to support the allegations and factual contentions in the Omni complaints, consistent with Rule 11(b).^{FN6} *Id.* at 18-21, 30. For these reasons, the court concluded that it was necessary to closely examine the facts alleged in Plaintiffs' Omni complaints. *Id.* at 26-28, 34.

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FN6. On June 21, 1996, in reply to the court's request for a response under Rules 9(b) and 11(b)(3) regarding the conspiracy and fraud claims, the PLC filed a two-volume, 750-page document titled "Memorandum of Law and Particularized Statement of Facts in Opposition to Defendants' Motions to Dismiss the Fraud and Conspiracy Claims in the 'Omni' Complaints". This submission was accompanied by a fifteen volume, 344-exhibit appendix containing thousands of pages.

On May 10, 1996, the PLC moved to voluntarily dismiss, from every complaint, claims seeking relief under the federal Magnuson-Moss Warranty Act ("Magnuson-Moss"), 15 U.S.C. § 2301 *et seq.*, and all state law claims of enterprise liability, market share liability, and alternative liability. On June 26, 1996, to ensure that Plaintiffs who did not join the PLC's motion had an opportunity to object to the dismissal of these claims, the court ordered Plaintiffs to show cause within ten days why the enumerated claims should not be dismissed. (Pretrial Order No. 420.) No documents have been filed in response to that Order. The court also has granted Defendants' motion to dismiss Plaintiffs' additional claims of fraud on the marketplace. (Tr. 6/24/96 at 80-81.)

After examining the PLC Omni Actions in the light of the relatively fundamental rules of pleading in a civil action, the court has decided that allegations of subject matter jurisdiction in the PLC Omni complaints are pleaded so imprecisely that the court is uncertain as to whether it has subject matter jurisdiction. The court also believes that other fundamental pleading problems are inherent in the PLC Omni complaints and that the conspiracy and fraud allegations in the Lestelle Omni Actions are not properly pleaded. Rather than correct these deficiencies piecemeal, the court will dismiss all of the PLC Omni Actions without prejudice and grant the PLC Plaintiffs leave to amend the civil actions that are to remain here and not be refiled pursuant to Pretrial Order No. 441. The amendments in those actions, or the allegations in newly filed complaints under Pretrial Order No. 441, however, must conform to the pleading requirements set forth in both the Federal Rules of Civil Procedure *and* in Part II.B.6. of this Memorandum.

II. DISCUSSION

A. Pleading Subject Matter Jurisdiction

The Federal Rules of Civil Procedure require each pleading that sets forth a claim for relief to contain "a short and plain statement of the grounds upon which the court's jurisdiction depends." Fed.R.Civ.P. 8(a)(1). Because the federal courts are courts of limited jurisdiction, it is essential that the parties plead allegations of jurisdiction in strict accordance with the rules. This is so because the court must ensure that cases falling outside its limits are not carelessly gathered into the court's sphere due to hastily drafted generalizations concerning jurisdiction. As the United States Supreme Court has stated: "It is to be presumed that a cause lies outside this limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction." Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375, 114 S.Ct. 1673, 1675 (1994) (citations omitted). Accordingly, a court must dismiss a pleading that has not satisfied this burden. *See* Fed.R.Civ.P. 12(b)(1) (providing that a party may move to dismiss a claim for lack of jurisdiction over the subject matter); Fed.R.Civ.P. 12(h)(3) (requiring the court to dismiss an action "[w]henver it appears by suggestion of the parties or otherwise that the court lacks jurisdiction of the subject matter").

1. The PLC Omni Actions

*4 The PLC Omni Actions initially invoked the court's federal question jurisdiction, 28 U.S.C. § 1331, "to the extent that Plaintiffs seek relief for breach of warranty claims arising under the Magnuso[n]-Moss Warranty Act." (Compl.¶ 1.) Alternatively, they invoke the court's diversity jurisdiction, 28 U.S.C. § 1332, "because the amount in controversy as to each Plaintiff exceeds the sum of \$50,000.00, exclusive of costs and interest; and the claims by the individual Plaintiffs are asserted only against defendants who are residents of a different state from the Plaintiffs." *Id.* ¶ 2.

As stated above, the court has received no documents in response to its Order to show cause why Magnuson-Moss claims should not be dismissed. Therefore, the court, in the Order accompanying this Memorandum, will dismiss all such claims with prejudice from every complaint filed in this multidistrict litigation.

Because all federal claims are dismissed, the PLC

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Omni Actions do not arise under federal law. Thus, the court has subject-matter jurisdiction of all claims only if there is "complete diversity", that is, only if each Plaintiff was a citizen of a different state than was each Defendant at the time the complaint was filed. ^{FN7} Owen Equip. & Erection Co. v. Kroger, 437 U.S. 365, 373 (1978). Based on the present state of the Omni complaints, the court can not ascertain whether it has diversity jurisdiction. The PLC Omni Actions suffer from three troublesome defects in this regard.

FN7. Defendants have not moved to dismiss Plaintiffs' Omni complaints based on the argument that the matter in controversy is \$50,000 or less, exclusive of interests and costs.

First, the averment in the PLC Omni complaints that "the claims by the individual Plaintiffs are asserted only against defendants who are residents of a different state from the Plaintiffs" is a wholly unacceptable manner in which to plead the court's diversity jurisdiction. In cases in which one, two, five, or ten Plaintiffs are suing dozens of Defendants, the PLC simply may not shift to the court, or ultimately someday to a jury, the painstaking burden of sifting through this haystack of allegations-or, eventually, the evidence-to find the needle supporting diversity of citizenship between each Plaintiff and each Defendant. At the outset, all complaints must specify which specific Plaintiffs are suing which specific Defendants on which claims, unless *all* Plaintiffs are suing *all* Defendants, and if that is intended, it must be so alleged.

Second, the PLC Omni complaints aver that the individual parties are "residents" of a particular state. An individual's *residence* is irrelevant in determining diversity of citizenship; the only fact that matters is whether he or she is a *citizen* of a particular state. The citizenship of an individual is the state of his or her domicile; that is, the state in which he or she has a "true, fixed and permanent home and principal establishment, and to which he [or she] has the intention of returning whenever he [or she] is absent therefrom." Liakakos v. Cigna Corp., 704 F.Supp. 583, 586 (E.D.Pa.1988) (quoting Michelson v. Exxon Research and Eng'g Co., 578 F.Supp. 289, 290 (W.D.Pa.), *aff'd*, 745 F.2d 47 (3d Cir.1984)). The court previously has brought this matter to the PLC's attention, (Tr. 4/19/96 at 14-16), and has permitted them to correct this defect in an amended complaint. (Pretrial Order No. 441.) The PLC, however, also

has improperly pleaded the citizenship of many of the corporate parties by referring only to their state of incorporation. (Compl. ¶¶ 12-15, 34-39, 42-49, 61-62.) A corporation is a citizen of the states in which it has been incorporated *and* in which it has its principal place of business. 28 U.S.C. § 1332(c)(1). A person's state of residence in most cases is the same as that person's state of citizenship. In some cases, however, a person resides in one state but is domiciled in another. The possibility that an individual's states of residence and domicile may be different drives the requirement to allege, and ultimately prove, that an individual plaintiff's citizenship is diverse from every defendant.

*5 Third, the PLC Omni Actions refer to the citizenship of unincorporated associations by referring to one state as its "domicile." (Compl. ¶¶ 63-65.) An unincorporated association's states of citizenship are the states of citizenship of each of its members. Carden v. Arkoma Assocs., 494 U.S. 185, 195-96 (1990). Some of the unincorporated associations named as Defendants in the Omni complaints appear to describe nationwide membership. Consequently, neither the court (nor any party, for that matter), can tell if state-law tort claims against, for example, the Spinal Implant Manufacturers Group can support a federal court's subject-matter jurisdiction when such jurisdiction is based solely on § 1332(a)(1).

For the above reasons, it is easy to see that the PLC Omni Actions fail to comply with Rule 8(a)(1) because they do not contain an adequate "short and plain statement of the grounds upon which the court's jurisdiction depends." Because the PLC Plaintiffs have not established that the court has subject matter jurisdiction over the PLC Omni Actions, the court will dismiss those complaints pursuant to Rule 12(b)(1). The PLC shall comply with these requirements and all other applicable rules should they elect to amend their complaints or file new complaints pursuant to Pretrial Order No. 441.

2. The Lestelle Omni Actions

The Lestelle Omni Actions do not rely on a federal question to invoke this court's subject matter jurisdiction. Because it appears that the court has diversity jurisdiction over these cases, the court will not dismiss the Lestelle Omni Actions. Although allegations of citizenship are properly pleaded for the most part, the court will allow the Lestelle Plaintiffs to amend the complaints to cure any defective

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jurisdictional allegations in accordance with the guidelines set forth above. (See Compl. at 3 ¶ 2) (“All plaintiffs herein are diverse in state citizenship from all defendants herein; no plaintiff asserts a claim against any defendant which is a citizen of or deemed to be a citizen of the domicile of any plaintiff herein.”).

B. Pleading a Claim for Relief

In addition to a clear and concise statement of the court's subject matter jurisdiction, Federal Rule of Civil Procedure 8 requires each complaint to contain “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed.R.Civ.P. 8(a)(2). A pleading containing a claim that does not satisfy this standard is subject to dismissal under Rule 12(b)(6).

In determining whether it should dismiss a complaint in this context, the court must accept as true all of the complaint's well-pleaded allegations of fact, construe such allegations in the light most favorable to the plaintiff, and “determine whether under any reasonable reading of the pleadings, the plaintiff may be entitled to relief.” *Colburn v. Upper Darby Township*, 838 F.2d 663, 665-66 (3d Cir.1988), cert. denied, 489 U.S. 1065 (1989) (citations omitted). A court should not dismiss a claim under Rule 12(b)(6) unless “it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.” *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957) (footnote omitted).

1. Conspiracy

*6 The law of civil conspiracy is generally the same in every state in which it is recognized, although the fundamental elements of each state's law sometimes are phrased differently. See, e.g., *In re Asbestos Sch. Litig.*, 46 F.3d 1284, 1292 (3d Cir.1994) (“To prove civil conspiracy in Pennsylvania, ... a plaintiff must show ‘that two or more persons combine[d] or enter[ed] an agreement to commit an unlawful act or to do an otherwise lawful act by unlawful means.’ ... [P]roof of malice is an essential part of a cause of action for conspiracy” (quoting *Burnside v. Abbott Lab.*, 505 A.2d 973, 980 (Pa.Super.1985)); *Meineke Discount Muffler v. Jaynes*, 999 F.2d 120, 124 (5th Cir.1993) (stating that, under Texas law, “[a] claim for civil conspiracy has five elements: (1) two or more persons; (2) have an objective to be accomplished; (3) a meeting of the participants'

minds on the objective or course of action; (4) one or more unlawful, overt acts; and, (5) resulting damages.”) (citing *Massey v. Armco Steel Co.*, 652 S.W.2d 932, 934 (Tex.1983)); *Waldrep Bros. Beauty Supply, Inc. v. Wynn Beauty Supply Co., Inc.*, 992 F.2d 59, 62 (4th Cir.1993) (“Under South Carolina law, ‘[a] civil conspiracy ... consists of three elements: (1) a combination of two or more persons, (2) for the purpose of injuring the plaintiff, (3) which causes him special damage.’ ”) (quoting *Lee v. Chesterfield Gen. Hosp., Inc.*, 344 S.E.2d 379, 382 (S.C.1986)); *Okusami v. Psychiatric Inst. of Washington, Inc.*, 959 F.2d 1062, 1066 (D.C.Cir.1992) (“ ‘In the District of Columbia a conspiracy requires: an agreement to do an unlawful act or a lawful act in an unlawful manner; an overt act in furtherance of the agreement by someone participating in it; and injury caused by the act.’ ”) (quoting *Halberstam v. Welch*, 705 F.2d 472, 487 (D.C.Cir.1983)); *Kee v. National Reserve Life Ins. Co.*, 918 F.2d 1538, 1541 (11th Cir.1990) (“Civil conspiracy under Florida law requires a showing that two or more persons have taken concerted action to accomplish some unlawful purpose, or to accomplish some lawful purpose by unlawful means.”); *McKibben v. Chubb*, 840 F.2d 1525, 1533 (10th Cir.1988) (“The necessary elements for a civil conspiracy claim in Kansas are: ‘(1) two or more persons; (2) an object to be accomplished; (3) a meeting of the minds in the object or course of action; (4) one or more unlawful overt acts; and (5) damages as the proximate cause thereof.’ ”) (quoting *Stoldt v. City of Toronto*, 678 P.2d 153, 161 (Kan.1984)); *Keller v. Ray, Quinney & Nebeker*, 896 F.Supp. 1563, 1572 (D.Utah 1995) (“In order to prove a civil conspiracy [under the law of Utah], Plaintiff must show the following elements: ‘(1) a combination of two or more persons, (2) an object to be accomplished, (3) a meeting of the minds on the object or course of action, (4) one or more unlawful, overt acts, and (5) damages as a proximate result thereof.’ ”) (quoting *Israel Pagan Estate v. Cannon*, 746 P.2d 785, 790 (Utah Ct.App.1987)), cert. dismissed, 771 P.2d 1032 (Utah 1989).

*7 Despite the lack of uniformity in the language expressing the elements of a civil conspiracy claim, state conspiracy law generally requires the party seeking relief to allege, at a minimum, that each Defendant was a party to an agreement. No amount of verbosity or rhetoric, mixed with bare legal conclusions, can serve as a substitute for precise articulation, even in the simplest form, of this and every other essential element of a civil conspiracy claim.

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Even though Rule 8 contains no such express requirement, the United States Court of Appeals for the Third Circuit has required parties pleading conspiracy to do so with specificity. *See Shearin v. E.F. Hutton Group, Inc.*, 885 F.2d 1162, 1166 (3d Cir.1989); *Rose v. Bartle*, 871 F.2d 331, 365-66 (3d Cir.1989); *Black & Yates, Inc. v. Mahogany Ass'n, Inc.*, 129 F.2d 227, 231-32 (3d Cir.1941), *cert. denied*, 317 U.S. 672 (1942); *Lofthus v. Southeast Pa. Transp. Auth.*, 843 F.Supp. 981, 986 & n. 8 (E.D.Pa.1994). Thus, the pleader must "set forth the allegations that address the period of the conspiracy, the object of the conspiracy, and the certain actions of the alleged conspirators taken to achieve that purpose." *Shearin*, 885 F.2d at 1166.

a. The PLC Omni Actions

The two "conspiracies" alleged in the PLC Omni Actions fall far short of these minimum requirements. The PLC Plaintiffs allege that, under one conspiracy, the manufacturer Defendants made efforts to place spine fixation systems using pedicle screw fixation techniques into the stream of commerce to circumvent the FDCA's prohibitions concerning adulterated and misbranded devices. (Com pl. ¶ 111-12.) According to the complaint, the manufacturers' "efforts" were accomplished by obtaining FDA clearance to market and sell component parts of spinal fixation devices that the FDA had already rejected. *Id.* ¶ 114. The manufacturers did this by telling the FDA that the devices would be used for long bones when the manufacturers always had intended to sell the devices for use as a spine fixation system. *Id.*

The other conspiracy is a broader and more ambiguous scheme involving the "other Defendants," including distributors, doctor-promoters, regulatory consultants, and promotional centers. The contours of this second conspiracy are difficult to discern because of the complaint's imprecision and verbosity. The court believes that it attempts to allege that all of the "other Defendants" conspired to aid and abet the manufacturers' efforts to promote spinal fixation devices in violation of the FDCA. *Id.* ¶ 111. The distributors aided and assisted the primary manufacturer-in this case, Sofamor Danek ("Sofamor")-and the other manufacturers in violating the law. *Id.* ¶ 115. The regulatory consultants "assisted and encouraged" Sofamor to pursue its unlawful conduct and "fostered and promoted" Sofamor's illegal conduct. *Id.* ¶ 116. The doctor-

promoters organized and arranged appearances at society meetings to promote pedicle screw spine plate fixation systems and to publish research favorable to the industry. *Id.* ¶ 117. They also solicited and secured the promotional centers as joint venturers in the promotion and sale of these products. *Id.* The promotional centers, in return for promoting and selling the fixation systems, received substantial financial incentives from Sofamor and the other manufacturers. *Id.* The complaint goes on to allege a series of disconnected facts that have little or nothing to do with the elements of a conspiracy claim.

*8 The PLC Plaintiffs have conceded that the conspiracy claim in their Omni complaints fails to allege an agreement in which any of the Defendants participated. (Tr. 7/25/95 at 102-03.) As stated above, the PLC Plaintiffs cannot state a civil conspiracy claim upon which relief can be granted without pleading that each Defendant was a party to an agreement. Accordingly, the court must grant Defendants' motion to dismiss these claims under Rule 12(b)(6).

b. The Lestelle Omni Actions

The Lestelle Omni complaints are similar in format and organization to the PLC Omni complaints, but their conspiracy claim is narrower and involves fewer Defendants. The claim, viewed in a light most favorable to the Lestelle Plaintiffs, is as follows: The manufacturing defendants "acted in agreement." (Compl. at 18 ¶ 4.) The object of the agreement was to cause the pedicle screw devices to be presented to the health care providers as safe and effective and as properly tested so as to create an illegal market for the pedicle screw devices to insure the success of the devices and to establish a favorable market for the devices, for their own economic gain.

Id. ¶ 1. The conspirators made fraudulent misrepresentations and concealed material facts regarding the safety of their devices. *Id.* at 19 ¶ 5. Because of these misrepresentations and concealments, each Plaintiff was "fraudulently induced" to have the pedicle screw devices implanted in his or her spine. *Id.* at 20 ¶ 10. The factfinder could reasonably infer that the devices would not have been implanted if the implanting physician knew that the devices were defective, experimental, untested, or improperly tested. The implanted devices caused Plaintiffs to suffer an injury. *Id.*

The court finds that these facts do not state a

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conspiracy claim upon which relief can be granted. Alleging that Defendants "acted in agreement" is a near miss if the Plaintiffs are intending to allege a conspiracy. Did Defendants agree or not? In addition, because the Lestelle Plaintiffs have alleged a conspiracy to defraud, they must do more than allege a short and plain statement showing that they are entitled to relief and set forth the specific facts of the conspiracy that the Third Circuit has required. They also must aver the circumstances of the fraud with particularity. Fed.R.Civ.P. 9(b). This requirement is not an alternative to the commands of Rule 8, but is a supplement to that rule.

In Shapiro v. UJB Fin. Corp., 964 F.2d 272 (3d Cir.), cert. denied, 506 U.S. 934 (1992), the Third Circuit stated that a party avers fraud consistent with this rule when it pleads five elements. The plaintiff must "plead (1) a specific false representation of material fact; (2) knowledge by the person who made it of its falsity; (3) ignorance of its falsity by the person to whom it was made; (4) the intention that it should be acted upon; and (5) that the plaintiff acted upon it to his damage." *Id.* at 284; Republic Envtl. Sys., (PA), Inc. v. Reichhold Chems., Inc., 154 F.R.D. 130, 131 (E.D.Pa.1994).

*9 The court finds that the Lestelle Omni complaints include only three of the five elements that are required for averring fraud under Rule 9(b) and Shapiro. In particular, the Lestelle Omni complaints fall short of the first and third elements. The complaints mention general categories of information that Defendants allegedly misrepresented, such as "risks, hazards and damages associated with their pedicle screw devices, and that said devices were experimental, untested and/or improperly tested and defective," but they fail to point to a *specific false representation of material fact*. The complaints also do not allege that the persons to whom an alleged fraudulent representation was made were ignorant of the statements' falsity.

For these reasons, the court will dismiss the conspiracy claims in the Lestelle Omni Actions pursuant to Rules 12(b)(6) and 9(b) because they have failed to set forth a claim upon which relief can be granted.

c. Dismissal Without Prejudice

The court, having granted a motion to dismiss under Rule 12(b)(6), must now decide whether the dismissal should be with prejudice or without

prejudice. The court has many factors to consider in making this determination. For the following five reasons, the court believes that a dismissal without prejudice is the fairest result at this time.

First, the court believes that the failure to state a conspiracy claim upon which relief can be granted is due primarily to inadequate pleading. The court can not, at this time, state with certainty that the PLC Plaintiffs have no basis to state a conspiracy claim against Defendants. It is simply not fair to preclude hundreds of Plaintiffs from forever pursuing a conspiracy claim because the drafter of the PLC Omni complaint form failed to meet the standards that the court requires in drafting the complaint. See 5A Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1357, at 360-65 (2d ed. 1990) ("A dismissal under Rule 12(b)(6) generally is not final or on the merits and the court normally will give plaintiff leave to file an amended complaint. The federal rule policy of deciding cases on the basis of the substantive rights involved rather than on technicalities requires that plaintiff be given every opportunity to cure a formal defect in his pleading. This is true even though the court doubts that plaintiff will be able to overcome the defects in his initial pleading.") (footnote omitted).

Second, this litigation is both legally and factually complex. This is not a class action, but rather a consolidation of seven thousand claimants in more than 1,650 complaints that about seventy district courts have transferred to this court for pretrial administration. Many of the claims based on state law were dismissed by this court in Pretrial Order No. 291 and now are subject to reevaluation and reinstatement in view of the United States Supreme Court's recent decision in Medtronic, Inc. v. Lohr, 116 S.Ct. 2240 (1996). This court believes that some of the flaws in the PLC Omni complaints are inherently fundamental and could have been avoided. Others, however, are not, and are entitled to be excused because they appear to be the result of good-faith innovation by necessity. In addition, hundreds of civil actions claiming damages from the use of screws in the pedicle of the spine have been filed in state courts in accordance with state pleading procedures. Many of these actions have been removed to this court under the federal removal statute. The difficulty in harmonizing state and federal pleading requirements, local rules of civil procedure, and the customs and practices that differ among the federal judicial districts oftentimes does not lend itself to easy decisionmaking, especially when efforts are made to combine into one complaint

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all of these variant requirements from all of these sources. It could very well be that another transferee court might feel differently about some of the points this court is making in this Memorandum. The cases are here, however, and this court must make the decisions on these matters, even though some practices might be acceptable in other districts or, indeed, revisited by a transferor court after remand. These circumstances warrant, in the court's view, an approach that is girded with restraint and reasonableness.

*10 Third, thousands of claims are at stake here and a dismissal with prejudice would have a devastating effect. The court disfavors dismissal at this early stage in the case because it believes that Plaintiffs should be permitted to allege a conspiracy claim, if it can properly be done, and that its merits should be tested through appropriate motion practices, discovery, and trial, as each of those steps becomes necessary. The court believes it is not fair to slam the door on the Plaintiffs' chances for recovery simply because their lawyers did not, or could not, express their claims consistently with the pleading rules.

Fourth, permitting Plaintiffs to amend their complaints will not prejudice Defendants because discovery has, in good measure, been stayed in all Omni actions, although the parties have used discovery obtained from other actions in the Omni cases. Because the Omni cases are at the pleading stage, and discovery will not have to be redone or reformed to conform to the proper pleading, prejudice to Defendants concerning completed discovery is not a major concern.

Fifth, the court, by Pretrial Order No. 441, has allowed Plaintiffs who must be dropped under Federal Rule of Civil Procedure 21 due to misjoinder, to refile their complaints in proper venues. Those complaints will be transferred to this court for continued inclusion in this litigation. The time period that is necessary to accomplish such proper joinder, which will include time to file new complaints, can also be used to amend or restructure the Omni complaints. Thus, the repairs to the Omni complaints will not delay the administration of this case or prejudice the rights of any party.

The court notes that Defendants have raised a number of substantive challenges to Plaintiffs' conspiracy claims. Some of these attacks appear to be meritorious and might support a dismissal, with prejudice, of a properly pleaded conspiracy claim.

The court believes, however, that it can only test Defendants' arguments against a conspiracy claim that complies with the pleading requirements of the Federal Rules of Civil Procedure. Only then can the court and the parties assess whether the claims have sufficient merit to proceed to the next stages of this litigation.

For the foregoing reasons, the court will dismiss the conspiracy claims without prejudice. As to the PLC and Lestelle Plaintiffs who need not file new complaints because they were properly joined according to Pretrial Order No. 441, including the PLC Plaintiffs whose complaints are dismissed today under Rule 12(b)(1), those Plaintiffs may include conspiracy claims in the amended complaints they were required to file under Pretrial Order No. 441. As to the PLC and Lestelle Plaintiffs who were improperly joined and were required by Pretrial Order No. 441 to file new complaints, those Plaintiffs may include conspiracy claims in their newly filed complaints. As to the Lestelle Omni Actions that included misjoined Plaintiffs, and that must be filed separately pursuant to Pretrial Order No. 441, the PLC and Lestelle Plaintiffs may include conspiracy claims in their newly filed complaints. All conspiracy claims in either of these two categories must comply with the requirements set forth below in Part II.B.6.

2. Fraud

*11 The PLC and Lestelle Omni complaints allege claims under the heading of "Fraud on the Marketplace." Essentially, this claim alleges that the Defendants published articles, sent letters, and wrote articles to physicians that knowingly misrepresented the FDA status of pedicle screw devices and the safety and efficacy of those devices. The court has dismissed all claims under the rubric of "fraud on the marketplace" in the Order accompanying this Memorandum. (Tr. 6/24/96 at 80-81.) This is the only fraud claim in the PLC Omni Actions.

The Lestelle Omni Actions, however, contain a different fraud claim that is buried within the conspiracy claim. This claim alleges: "The defendant manufacturers, *individually* and in concert, suppressed, concealed and misrepresented information about the risks, hazards, and damages associated with their pedicle screw devices, and that said devices were experimental, untested and/or improperly tested and defective, in an effort to promote the use of their devices[.]" (Compl. at 19)